



## **NOAA Seafood Inspection Program**

The NOAA Seafood Inspection Program is updating its HACCP-based Inspection Program and would like comments from Program participants and other interested parties. The Program management believes the proposed changes will provide a more efficient and acknowledged system which will ultimately better serve the industry. Outlined below are the major changes to the program for quick review. Comments are requested by May 15, 1999 and should be sent to:

Steven Wilson  
Chief Quality Officer  
NOAA Seafood Inspection Program  
1315 East-West Highway  
Silver Spring, Maryland 20910  
Phone: 301-713-2355  
FAX: 301-713-1081  
E-mail: [Steven.Wilson@noaa.gov](mailto:Steven.Wilson@noaa.gov)

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### **Major Proposed Changes**

#### Quality Management Principles

Based upon the Codex Food Hygiene Code of Practice, HACCP plans, Defect Plans and Sanitation Standard Operating Procedures are all a portion of the quality manual firms will have to provide. Much of this information is already part of the current program requirements, but adopting the principles set forth by Codex as well as adopting a quality management standard will strengthen to program's commitment to quality as well as safety, wholesomeness, and economic integrity.

#### User Friendly Format

The format of the document will change to be more user friendly. We will combine the program requirements in the manual release and the submission guide to make the writing of the HACCP plans easier and to provide the participant with an easier to use guidance document. The annexes will then be limited to a sample quality manual, the checklist and its guidance, and the guidelines for an overall quality management system. In this way, the document can be better used as a training document and a study guide. Less detail of work procedures in the firm's quality manual and more attention to quality policy will make revisions to the firm's policies and procedures easier to perform, track, and will ultimately be less burdensome. Seafood Inspection Program personnel will assist the current program participants in making any necessary changes to their plans.

### Change of Frequency

This change will provide a more uniform audit frequency and was highly requested by the industry.

Below are the Levels in the current HACCP-based Inspection Program:

Systems Audit Frequency Schedule			
Facility Rating	Vessel Systems Audit Frequency	Processor Systems Audit Frequency	Systems Audit Frequency
Level I	Once every eighth trip*	Once every six months	Once every eighth trip*
Level II	Once every fourth trip*	Once every two months	Once every fourth trip*
Level III	Once every other trip*	Once every month	Once every other trip*
Level IV	Once every trip	Once every two weeks	Once every trip
Level V	As necessary	Daily	As necessary

\* An on-board Systems Audit for facilities at these Levels shall be conducted on a frequency of not less than annually.

Qualifying Visits for Next Higher Level			
Facility Rating	Vessels	Processors	Retail and Food Service
Level I	NA	NA	NA
Level II	2	3	2
Level III	2	2	2
Level IV	2	2	3
Level V	NA	NA	NA

This is the proposed audit frequency:

Systems Audit Frequency			
Facility Rating	Normal	Reduced	Requirements to be Audited at a Reduced Frequency
Vessels	Once every other trip*	Once every fourth trip	Three consecutive audits with no Serious or Critical Deficiencies
Processors	Once every month	Once every other month	Six consecutive audits with no Serious or Critical Deficiencies
Retail and Food Service	Once every calendar quarter	Once every six months	Two consecutive audits with no Serious or Critical Deficiencies

\*A audit of a trip will consist of ten percent of the total trip days. If for example the trip is 30 days, the audit will consist of three days during the trip.

### Sanitation Evaluation Updated

The recent FDA HACCP and Sanitation regulations outlined eight areas of sanitation that the firm must monitor and provide documentation. The Seafood HACCP Alliance has been developing a one-day training session to assist industry in developing their Sanitation Standard Operating Procedures for these eight areas. The Seafood Inspection Program has been very active in this activity and as such has modified their audit checklist to conform to these eight areas of sanitation. Seafood Inspection Program personnel will assist the industry in making the necessary adjustments, if any.

### Use of Recognized Audit Principles and Procedures

The auditors from the Seafood Inspection Program will use internationally recognized standards as their audit procedures. The use of these standards will provide for a more uniform auditing practice and will assist in defining internationally recognized practices in the evaluation of product, records and systems. Where applicable, recognized statistical methods and quality management principles will be used. In this way, the Seafood Inspection Program personnel will be better equipped to provide sound quality system and management assistance to the industry and the program participants.

### Records Assessment and End Item Evaluation

Records reviews will be separated from the end item evaluation during an audit. Each will play a role in the determination of the firm's success in following their quality plan. The new design minimizes the review of records to only those samples necessary as well as minimizes the routine end item evaluation of product. However, as usual, if specific circumstances dictate, additional samples of records or product or both may be necessary.

### Laboratory Analyses

The use of analytical testing is being thoroughly reviewed based upon an assessment of risks and the past results. Although the information is not yet complete, it is expected that a more defined approach for both the industry and Seafood Inspection Program personnel will prevail.

# **NOAA HACCP-based Quality Management Program**

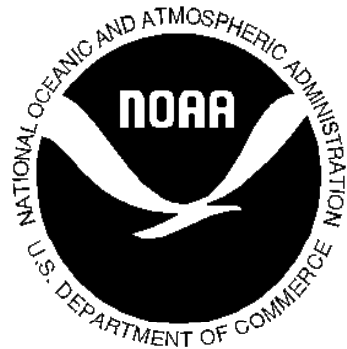
## **Program Participants Guide**



National Marine Fisheries Service

### **Seafood Inspection Program**

1315 East-West Highway  
Silver Spring, Maryland 20910



# NOAA HACCP-based Quality Management Program

## **Authority**

Authority for the Seafood Inspection Program to provide this HACCP-based Quality Management Program can be found in 50 CFR 260.103

## **Introduction:**

HACCP (Hazard Analysis Critical Control Point), is a non-traditional, non-continuous inspection technique recommended by the National Academy of Sciences as a more scientific, analytical, and economical approach than that provided by traditional inspection and quality control methods. HACCP, which focuses on problem prevention and problem solving, relies heavily on proper monitoring and record keeping by the industry. One of the primary economic benefits of HACCP is that it provides for reduced destructive sampling of the finished product as compared to the end-product sampling required under traditional inspection systems. The application of HACCP principles to seafood inspection has been adopted by several countries, including Canada, Iceland, and the European Union, and is becoming more broadly recognized by the international community as a mechanism to apply uniform inspection procedures.

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

In July 1992, NMFS published a Federal Register notice announcing the availability of a new seafood inspection program based on Hazard Analysis Critical Control Point (HACCP) principles. This program is in addition to the Integrated Quality Assurance (IQA) Program that also uses HACCP principles. However, the IQA program, having

unique methods for the inspection and grading of products, will continue as an option for applicants to the program.

The guidelines for the HACCP-based Quality Management Program have been compiled to inform interested parties that the NMFS is offering an alternative inspection program in addition to what is presently available. Participation in one program over the other is a decision, which must be made by the company's management. Under the Quality Management Program, the company takes on the responsibility of documenting and implementing a quality system. NOAA will then ensure that the quality system in place is adequate to control the critical functions by regular inspections of the system, known as audits. These audits will evaluate the quality system by examining product, processes, and records.

This document includes sections, which explain the specifications or requirements of the QMP program for documenting a quality system that will meet NMFS requirements. The document is also a guide manual for use by interested parties in developing their own quality manual. The HACCP-based Quality Management Program will allow participants an opportunity to apply their existing quality systems more efficiently, receive the management benefits of producing safe, wholesome, and properly labeled products more consistently and obtain the marketing benefits of using marks associated with the program.

In summary, the HACCP-based service is consistent with global activities to harmonize inspection protocols. In addition, NOAA believes that the HACCP-based service will enhance the safety, wholesomeness, economic integrity, and quality of seafood available to consumers, as well as improve seafood industry quality assurance and regulatory oversight.

## **Scope:**

NOAA policy is to encourage and assist interested parties in the development and

implementation of HACCP-based quality management systems to facilitate consistent distribution of safe, wholesome, and properly labeled fishery products of desired uniform quality. The development and implementation of HACCP-based quality management systems is optional. However, their use should result in more efficient use of NOAA resources to inspect, grade, and certify fishery products. This document is designed to provide guidance for the development, implementation, and operation of HACCP-based quality management systems, which will meet NOAA approval.

#### **Definitions:**

1. **Auditee:** The organization being audited.
2. **Auditor:** A person qualified to perform audits.
3. **Contamination:** The occurrence of a contaminant in fish due to microbial pathogens, chemicals, foreign bodies, spoilage, objectionable taints, unwanted or diseased matter, which may compromise fish safety or suitability.
4. **Control measure (preventive measure):** Action performed to eliminate a hazard or reduce it to an acceptable level. For the purposes of this guide a control measure is also applied to a defect.
5. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
6. **Corrective Actions:** An action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
7. **Critical Control Point (CCP):** A point, step, or procedure in a food process at which control can be applied, and a food hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
8. **Critical Deficiency:** A hazardous deviation from plan requirements such that maintenance of the safety, wholesomeness, and economic integrity is absent; will result in unsafe, unwholesome, or misbranded product.
9. **Critical Limit:** The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point, or defect action point, to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
10. **Decision Tree:** A sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs. For the purpose of this Program this also applies to a DAP.
11. **Decomposition:** A persistent and distinct objectionable odor or flavor including texture breakdown caused by the deterioration of fish.
12. **Defect:** A condition found in a product which fails to meet essential quality, composition and/or labeling provisions of the appropriate product standards or specifications.
13. **Defect Action Point (DAP):** A point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated.
14. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
15. **HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety and control of defects which are significant for essential quality, composition, and/or labeling provisions in the segment of the food chain under consideration.
16. **Hazard:** A chance for, or the risk of, a biological, chemical, physical, or economic property in a food product that could violate established program criteria or cause the consumer distress or illness.
17. **Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
18. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.

19. **Major Deficiency:** A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
20. **Minor Deficiency:** A failure of the part of the HACCP-based system relative to facility sanitation which is not likely to reduce materially the facility's ability to meet acceptable sanitation requirements.
21. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the firm to report the findings at each CCP or DAP.
22. **NUOCA (Notice of Unusual Occurrence and Corrective Action):** The record that outlines the incident and the corresponding corrective action implemented by the facility.
23. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
24. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
25. **Preventive Measure(s) (control measure):** Physical, chemical, or other factors that can be used to control an identified food safety hazard. For the purposes of this program, this also applies to a DAP.
26. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
27. **Quality:** Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. The inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.
28. **Quality Audit:** A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
29. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
30. **Serious Deficiency:** A severe deviation from plan requirements such that maintenance of safety, wholesomeness, and economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, unwholesome, or misbranded product.
31. **Severity:** The seriousness of the effect(s) of a hazard or defect.
32. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
33. **High risk products:** Seafood that may pose a significant danger to the health of the public when prepared for consumption by conventional or traditional means. For example, ready-to-eat; heat and/or brown and serve products; products which may contain a microbial pathogen, biotoxin, or physical or chemical contaminant which may pose an unacceptable health risk at the time of consumption.
34. **Systems Audit:** On-site NMFS evaluation of the firm's effectiveness in following the plan after validation.
35. **Validation:** That element of verification focused on collecting and evaluating scientific and technical information to determine if the Quality Management Plan, when properly implemented, will effectively control the hazards and defects.
36. **Verification:** Those activities performed by the firm, other than monitoring, that determine the validity of the Quality Management Plan and that the system is operating according to the plan.

#### **Applying to Enter the Program:**

Firms who wish to participate in the Program may apply orally or in writing to the appropriate Regional Inspection Branch. If application is made orally, it must be confirmed promptly in writing. The Regional Inspection Branch will provide the applicant with all necessary materials to inform them of the program and its requirements. This material will also include the requirements and any policies necessary for

development and submission of a Quality Management Plan. The firm develops its Quality Management Plan and submits it for review according to the plan review procedures described further in this document.

**NOTE:** Firms who wish to have a more in-depth presentation of the Program and its requirements may request a meeting of all interested parties. This may incur a cost and should be discussed with the Regional Inspection Branch.

### **Education and Training**

The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information concerning the control of food borne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP and quality management is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP or DAP.

Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP or quality plan. *Each facility must employ a NOAA-certified person knowledgeable in the program's principles to be present during all processing times. The certification must be kept on file and available to NOAA at all times.*

**NOTE:** Retail establishments of significant size do not require the certification of an individual at each store or facility location. However, they must have demonstrated sufficient control of the training of all pertinent individuals and have a sufficient number of management personnel trained and certified in their system to maintain proper control of the concepts and the HACCP plan.

### **Plan Review and Approval**

Each applicant must submit a QMP plan in accordance with this document. At the request of the firm, NOAA will provide consultation toward the development of the HACCP-based Quality Management Program plan on a fee basis.

Plans are submitted to the servicing Regional Inspection Branch for desk review. Reviews of the plan may require requests for changes, clarifications, deletions, etc., from the firm. The servicing region will work with the firm to finalize the development of the QMP Plan. A written review is sent to the firm indicating what changes, if any, are necessary prior to Validation. All work of the assigned CSO and the Regional Inspection Branch is performed on a fee basis at established rates.

After the QMP plan has been validated, modifications may be made under the following conditions. The firm must notify the servicing Regional Inspection Branch, in writing (Faxes are acceptable), of any modifications in their QMP plan before implementing the changes. However, any changes to address a health or safety issue may be made without prior approval, but must be documented in a corrective action plan. The Regional Inspection Branch must be notified of these immediate changes within one working day.

### **Label Review Procedures**

All applicable labels must be approved prior to use in accordance with Part I, Chapter 3, Section 5 of NOAA Handbook 25, Inspection Manual.

### **Validation**

The firm should begin following their plan as soon as possible. The firm must adhere to the plan's provisions and keep all records associated with the approved QMP plan for at least five (5) consecutive production days. The firm will contact the Regional Inspection Branch as soon as they believe the approved plan is functioning successfully and when they have records covering the minimum production days. The Regional Inspection Branch will schedule a Validation with the firm. The firm must verify through end-product examination that the process controls result in product which complies to all

regulations and applicable quality standards or specifications. If documentation has not been previously provided, the firm must collect data prior to the Validation which will be sufficient to demonstrate this relationship. Firms attempting to document this relationship must collect data on not less than 20 percent of their lots using sampling plans comparable in statistical confidence to those in 50 CFR Part 260, with at least one lot representing each product form. The inspection records must be available to NMFS at the validation. Although not required, NMFS recommends that the firm submit end-item verification records with their QMP Plan. This will allow the firm to test their controls, provide plan reviewers more information, and possibly reduce the Validation time and cost.

The Validation will determine whether all of the hazards/defects and CCPs/DAPs have been identified, the quality management plan is being followed and monitored by the firm, and is effectively controlling the identified hazards/defects. The Validation will be conducted on a fee basis by a team of personnel assigned based upon the needs of the validation and the expertise available. The number and structure of the team will be determined by the size and complexity of the firm's process and nature of hazards associated with the products covered under the QMP Plan. The validation will include conducting paperwork reviews, recording sanitation and in-process observations and product verification. All reviews will be performed using accepted auditing practices based on the standards of ISO 10011 Parts 1 and 2. Conducting a combination of statistical reviews of records and finished product sample inspections will complete product verifications. At least one lot for each product form will be verified by inspecting samples of finished product. NMFS inspection personnel may, for cause, sample and verify product in excess of this guideline. Firms will be rated using the Systems Audit Checklist. If the firm is determined to be acceptable it will qualify as a participant in the program and may finalize a contract for services with NMFS. If a firm passes its Validation, all products under review during the Validation, including the previous five (5) production days,

are eligible to bear the appropriate official marks or advertising claim.

**Note for Vessels:** Due to logistical factors, only one NMFS Consumer Safety Officer will perform the Validation. The NMFS Consumer Safety Officer will accompany the vessel, if determined necessary, for an appropriate time period during a fishing season, performing the background checks of critical control points and validating the plan at one time. The officer may assist the quality assurance/management group on board the vessel in any alterations to make to their QMP Plan to work toward plan approval and a successful Validation. Once the QMP plan is validated, the officer is taken off the vessel as soon as is practicable. These procedural accommodations are made in recognition of possible space restrictions and to reduce the numbers of transfers at sea.

#### **QMP Plan Changes**

As the QMP Plan outlines the basic foundation and policies of the firm's quality program, changes to the plan must be approved in advance with Program management. However, the specific work procedures may change as necessary without prior approval, as long as they meet the Program Quality Standard. Prior to signing the contract, it will be determined what of the firm's document requires pre-approval.

#### **Systems Audits**

Only with a valid contract and continued demonstrated compliance with all applicable laws and regulations and policies may 1) the firm be eligible to use official marks or other related statements and 2) firm-collected data be used by NMFS towards issuing official certification of the firm's products or facility compliance. After the firm's QMP Plan is validated, NMFS will conduct Systems Audits at a frequency listed below to determine the firm's continued adherence to their QMP Plan.

#### *Vessels*

Firms must provide the appropriate NMFS Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Firms must give

the Port NMFS Consumer Safety Officer notice prior to each port arrival, providing sufficient time for the Officer to verify and audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program. Vessels will be visited once every other trip, with at least one visit per year. If no Serious or Critical deficiencies are found for three consecutive audits, the vessel will be visited once every fourth trip until a Serious or Critical is found.

A visit will be composed of a minimum of one percent, to a maximum of ten (10) percent of, the scheduled fishing days for the trip in question. For example, if a trip is scheduled to last 30 days, the Systems Audit will be performed over approximately three days. Additional days may be necessary if the Consumer Safety Officer has encountered a problem during the audit. Audits may not require the auditor to be on board during fishing, but will require the auditor to be present during off-loading.

**NOTE:** Samples of finished product may be pulled while the NMFS Consumer Safety Officer is on board or at dockside. If samples are pulled while on board, they will be evaluated immediately for compliance.

#### *Processing Establishments*

NMFS will conduct unannounced Systems Audits to determine the firm's continued

adherence to their plan. Facilities will be visited once every month. If after six months of operation no Serious or Critical deficiencies have been assessed, firms will be visited once every other month until a Serious or Critical is found.

#### *Retail and Food Service Establishments*

NMFS will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan. Facilities will be visited once every calendar quarter. If after two consecutive calendar quarters no Serious or Critical deficiencies have been assessed, facilities will be visited once every six months until such time as a Serious or Critical deficiency is found.

**NOTE:** NMFS is interested in providing this program with a minimum possible burden to retail participants. Record keeping should not be so grand as to cause undue hardship on the retailer. Records should be of a precision only to show what products were received by what supplier on a particular day.

#### *Procedures for Chains with an Established Quality Assurance Program:*

Firms which operate a chain of stores may have the stores under the program sampled as outlined in Table 2 (provided they have an established approved Quality Assurance System).

Table 1--Systems Audit Frequency			
Facility Rating	Normal	Reduced	Requirements to be Audited at a Reduced Frequency
Vessels	Once every other trip*	Once every fourth trip	Three consecutive audits with no Serious or Critical Deficiencies
Processors	Once every month	Once every other month	Six consecutive audits with no Serious or Critical Deficiencies
Retail and Food Service	Once every calendar quarter	Once every six months	Two consecutive audits with no Serious or Critical Deficiencies

\*An audit of a trip will consist of ten percent of the total trip days. If for example the trip is 30 days, the audit will consist of three days during the trip.

Table 2		Stores to Sample Per Calendar Quarter	
Number of Facilities	Reduced	Normal	Tightened
2 - 4	1	2	ALL
5 - 8	3	4	5
9 - 12	4	6	8
13 - 16	6	8	10
17 - 20	8	10	13
21 - 30	9	13	18
31 - 40	10	15	21
41 - 70	10	18	25
71 - 100	10	19	30
101 or more	10	20	35

In addition the following criteria apply:

- 1) All firms will begin at Tightened sampling. After two successive calendar quarters the firm will move to Normal sampling. After two successive calendar quarters at Normal sampling, the firm will move to reduced sampling.
- 2) No stores in the sample may be considered unreliable. If a store in the sample is deemed unreliable (Five Serious deficiencies or One Critical deficiency), the Firm's Quality Assurance System is suspect. NMFS will perform an audit on the total Quality Assurance System for the next thirty days. This audit will include the sampling of additional stores.
- 3) If after the audit the Quality Assurance System is deemed under control, the firm will be sampled at the Tightened level and the system begins again.
- 4) If the Quality Assurance System is deemed to not be performing as designed, Regional Management Regional Management and the Quality Team will evaluate the companies entire program and suggest the necessary changes to continue in the Program. This evaluation may result in a permanent or temporary removal from the program.
- 5) During this thirty day period the stores may continue to use all advertisement claims.
- 6) If the sample of stores does not meet the above requirements, then each store in the chain must be audited on its own until such

time as the Quality Assurance System has been re-approved.

#### ***Procedures for Firms Which Are Considered Unreliable***

A firm that has been determined unreliable has demonstrated difficulties in administering their QMP Plan. If a Consumer Safety Officer rates a facility unreliable, he/she will rate the facility and immediately contact his/her Supervisor. The decision to rate a facility unreliable will be made prior to the Consumer Safety Officer performing the exit interview. Once the rating is confirmed, the Chief Quality Officer is to be informed and provided with all documentation, including but not limited to: Final Audit Report, scoresheets, supporting documentation, etc. Facilities who are rated unreliable have a period of thirty days to remove the unreliable status. Failure to do so will result in the facility's removal from the NMFS HACCP-based Inspection Program, or the EU HACCP Program. A firm who is deemed unreliable may continue to use the mark or other applicable advertising privileges if consent by NMFS is given for daily auditing of the firm. Consent will be on a case by case basis and granted only if NMFS believes the nature of the condition which caused the firm to become unreliable warrants daily auditing. Daily auditing will be acceptable to NMFS under the following conditions:

- a. The firm must submit a corrective action plan to the NMFS Consumer Safety Officer detailing how they will correct the

problem (Faxes are acceptable). The corrective action plan must include, at a minimum, detailed descriptions of the following:

- 1) A statement of the problem
- 2) Identification of the person or persons handling the situation
- 3) The methods to be used to correct the problem
- 4) A schedule which details the time frame to correct the problem
- 5) A statement with signatures of top management attesting to their commitment to correct the deficiency

The corrective action plan must be written in sufficient detail to provide NMFS with all necessary information for its approval or disapproval.

- b. The NMFS Consumer Safety Officer will review the corrective actions identified by the firm and will approve or disapprove the corrective actions and notify his/her Supervisor. Daily auditing will continue until the issue is corrected for a maximum of thirty calendar days.
- c. Products may be certified during daily auditing. However, if any condition(s) exists that is considered critical, no product certification will occur until the condition is corrected to the satisfaction of NMFS.
- d. At the inspector's discretion, product compliance will be verified by end-item inspection. No products covered by the QMP plan will leave the firm without NMFS approval.
- e. Firms deemed unreliable twice in a twelve month period will be removed from the HACCP-based Quality Management Program or the EU HACCP Program.
- f. Firms who have been removed from the HACCP-based Quality Management Program or the EU HACCP Program may submit a request for reapplication into the program after a period of three calendar months. Application will be accepted by NMFS only if evidence of a change in management philosophy can be provided.

- g. Firms who have been removed from the NMFS HACCP-based Quality Management Program or EU HACCP Program may still be eligible to enter into the traditional Inspection Program.

### ***Appeal Procedures***

If a facility wishes to appeal this decision, they are to contact, in writing, the Chief Quality Officer in the headquarters office. The facility must provide, in writing, all pertinent information as to why it is believed the rating was determined in error and what the facility expects to be a proper correction. Once the Chief Quality Officer receives all information, he/she will investigate the matter and make a determination. The decision will be communicated to the Regional Inspection Branch and the facility as soon as it is made. A written report will follow.

### ***Use of Marks***

Participating firms are responsible for using the marks in accordance with the regulations set forth in 50 CFR Part 260 and the Policy and Guidelines for Advertising and Marking Products Inspected by the U.S. Department of Commerce. Facilities who have received official stamping devices must have written procedures in place securing the device and protecting from its abuse.

### ***Analytical Testing and Product Verification***

The firm must perform periodic end-item verification of product compliance to program requirements. Both the firm and NMFS must agree upon frequencies and end-item requirements. In addition samples for analytical testing must be collected and tested at least once per year as part of their verification procedures. The level of analytical sampling per lot must be comparable to that found in Tables 1 and 2. Records of all analytical findings will be made available to NMFS inspectors during Systems Audits and at other times as necessary.

To determine whether the product produced at the firm meets specification and/or U.S. grade standard requirements, NMFS will routinely perform a product audit on up to three (3) lots produced by the firm since the last Systems Audit. This information will be used to guide the

auditor in his/her audit of the system. Product audits will be completed by conducting records reviews and finished product sample inspections.

Additional lots may be sampled if the situation warrants. Lots must be defined by the firm in their QMP plan and approved by NMFS.

Table 1: Number of Analyses per Commodity <sup>1</sup>										
Commodity	Product Risk <sup>2</sup>	Salmonella	Listeria	Staph Aureus	Fecal Coliforms	Aerobic Plate Count	Sulfites	Histamine	Methyl Mercury	Chlorinated Pesticides
Cooked shrimp	High	1	1	5	5		1			
Raw or raw breaded shrimp	Low						1			
Fully cooked warm-and-serve fish	High	1	1	5						
Cooked crabmeat or surimi	High	1	1	5	5					
Molluscan Shellfish	High					5				
Fresh water/near-shore marine fish	Low									1
Tuna, shark, or swordfish	Low								1	
Tuna, mahi-mahi, or mackerel	Low							6 (min)		

<sup>1</sup> A commodity includes all products produced under the same HACCP plan.

<sup>2</sup> Sampling Frequency:  
 High Risk Products - a maximum of six lots yearly  
 Low Risk Products - a maximum of three lots yearly

Table 2: Samples, Subs, and Composites Summary per Lot					
Analysis	Commodity	Sampling Plan	Subs	Sub Size	Composite
Chlorinated Pesticides	Fresh water/near-shore marine fish	FDA Guideline	12	1 pound	Yes, (12:1)
Methyl Mercury	Tuna, shark, or swordfish	FDA Guideline	12	1 pound	Yes, (12:1)
Sulfites	Shrimp	FDA Guideline	3	5 pounds	Yes, (3:1)
Histamine	Tuna, mahi-mahi, mackerel	Codex, 3 Class <sup>1</sup>	6 (min)	4 oz. (min) or 1 fish	No
Listeria and Salmonella	Cooked shrimp, crabmeat, surimi, and warm-and-serve fish	Revision to FDA Guideline	15	8 oz min.	Yes, (15:1)
Staphylococcus	Cooked shrimp and crabmeat	NACMCF <sup>2</sup>	5	8 oz. min.	No
	Warm-and-serve fish and surimi	Codex, 3 Class			
Fecal Coliforms	Cooked shrimp and crabmeat	NACMCF	5	8 oz. min.	No
Aerobic Plate Count	Molluscan Shellfish	NACMCF	5	12 shellfish in shell or 10 oz. (min.) package	No

1 Codex Sampling Plan with a 3 Class decision rule.

2 National Advisory Committee on Microbiological Criteria for Foods.

### Systems Audit Checklist

<b>Name and Address of Facility Audited</b>	<b>Region</b>
<b>Facility Owner (Company or Individual)</b>	<b>State</b>
<b>Products Concerned:</b>	<b>Facility Number</b>
<b>Name and Number of Lead Auditor</b>	<b>Date</b>
<b>Name and Title of Accompanying Individual</b>	<b>Phone Number:</b> <b>Fax number:</b>

Check this symbol if the deficiency concerns product at a High Risk stage--

<b>Hazard Analysis and QMP Plan</b>				
PROCEDURES	MIN	MAJ	SER	CR
1. Hazard/Defect analysis not performed or available.		<input type="checkbox"/>	<input type="checkbox"/>	
2. Hazard/Defect analysis not reassessed when indicated as necessary.			<input type="checkbox"/>	
3. HACCP/Defect Plan, SSOP's, and/or Quality Plan not followed.			<input type="checkbox"/>	<input type="checkbox"/>
4. Critical limits improperly identified.			<input type="checkbox"/>	
5. Critical limits not followed.				<input type="checkbox"/>
6. Monitoring procedures not followed.			<input type="checkbox"/>	
7. Corrective Action not taken.				<input type="checkbox"/>
8. Verification procedures not followed.			<input type="checkbox"/>	
RECORDS	MIN	MAJ	SER	CR
1. Records are not up-to-date.		<input type="checkbox"/>	<input type="checkbox"/>	
2. Records are inaccurate.			<input type="checkbox"/>	<input type="checkbox"/>
3. Records are not available for inspection.				<input type="checkbox"/>
4. Any documents or records are falsified.				<input type="checkbox"/>
5. Inadequate information on records. (Facility name and location, etc.)		<input type="checkbox"/>		
OTHER REQUIREMENTS	MIN	MAJ	SER	CR
1. HACCP plan not signed and/or dated by proper personnel.			<input type="checkbox"/>	
2. Hazard analysis, reassessment/modification of HACCP plan performed by untrained personnel.			<input type="checkbox"/>	
3. Records review performed by untrained personnel.				<input type="checkbox"/>
4. Program trained personnel not available.			<input type="checkbox"/>	
5. Modification to QMP plan without approval.			<input type="checkbox"/>	

Facility Sanitation				
<b>SAFETY OF PROCESS WATER</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
1.1 Unsafe or unsanitary water supply				<input type="checkbox"/>
1.2 No protection against backflow, back-siphonage, or other sources of contamination.			<input type="checkbox"/>	
1.3 Inadequate supply of hot water.	<input type="checkbox"/>			
1.4 Ice not manufactured, handled, or used in a sanitary manner.				<input type="checkbox"/>
<b>FOOD CONTACT SURFACES</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
2.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product contamination.		<input type="checkbox"/>		
2.2 Equipment and utensils not maintained in proper repair or removed when necessary. (Product contact surfaces.)		<input type="checkbox"/>	<input type="checkbox"/>	
2.3 Product contact surfaces not cleaned and sanitized before use, after interruptions, or as necessary.			<input type="checkbox"/>	<input type="checkbox"/>
2.4 Processing or food handling personnel do not maintain a high degree of personal cleanliness.		<input type="checkbox"/>	<input type="checkbox"/>	
2.5 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.			<input type="checkbox"/>	<input type="checkbox"/>
<b>PREVENTION OF CROSS CONTAMINATION</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
3.1 Grounds condition can permit contamination to enter the facility.	<input type="checkbox"/>			
3.2 Facility				
3.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized; does not preclude contamination.		<input type="checkbox"/>		
3.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.			<input type="checkbox"/>	<input type="checkbox"/>
3.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.				
3.3.1 Areas directly affecting product or primary packaging material.				<input type="checkbox"/>
3.3.2 Other.	<input type="checkbox"/>	<input type="checkbox"/>		
3.4 Cleaning methods permit adulteration or contamination.			<input type="checkbox"/>	<input type="checkbox"/>
3.5 Finished product not properly covered or protected.		<input type="checkbox"/>	<input type="checkbox"/>	
3.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-product contact surfaces)	<input type="checkbox"/>	<input type="checkbox"/>		
3.7 Non-product contact surfaces not cleaned before use.		<input type="checkbox"/>		

<b>HANDWASHING, HAND SANITIZING, AND TOILET FACILITIES</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
4.1 Handwashing and hand sanitizing stations not present or conveniently located.			<input type="checkbox"/>	<input type="checkbox"/>
4.2 Improper disposal of sewage..				<input type="checkbox"/>
4.3 Inadequate supplies.		<input type="checkbox"/>		
4.4 Insufficient number of functional toilets.	<input type="checkbox"/>			
<b>PROTECTION FROM ADULTERATION</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
5.1 Condensation:				
5.1.1 Areas directly affecting product or packaging material.			<input type="checkbox"/>	<input type="checkbox"/>
5.1.2 Other		<input type="checkbox"/>		
5.2 Adequate air exchange does not exist.	<input type="checkbox"/>			
<b>PROPER LABELING, STORAGE, AND USE OF TOXIC COMPOUNDS</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
6.1 Chemical(s) improperly used or handled.				<input type="checkbox"/>
6.2 Chemical(s) improperly stored.			<input type="checkbox"/>	
6.3 Chemical(s) improperly labeled.		<input type="checkbox"/>		
<b>CONTROL OF EMPLOYEE HEALTH CONDITIONS</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
7.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.			<input type="checkbox"/>	
<b>EXCLUSION OF PESTS</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
8.1 Harborage and attractant areas present.		<input type="checkbox"/>		
8.2 Pest control measures not effective:				
8.2.1 Exclusion.		<input type="checkbox"/>		
8.2.2 Extermination.			<input type="checkbox"/>	
8.3 Improper disposal of processing waste.			<input type="checkbox"/>	
8.4 Inadequate housekeeping.	<input type="checkbox"/>			
<b>SUMMARY</b>	<b>MIN</b>	<b>MAJ</b>	<b>SER</b>	<b>CR</b>
Total Deficiencies				
Maximum Deficiencies Permitted	<b>NA*</b>	<b>NA*</b>	<b>4</b>	<b>0</b>

Lead Auditor Signature and Date
Supervisor Signature and Date

## Systems Audit Checklist Guidance

### Adherence to HACCP-based Plan

#### A. PROCEDURES

The procedures outlined in a firm's QMP plan must be followed as written. The plan was approved by NMFS as a whole, not procedure-by-procedure. Not following a procedure could affect the entire critical control point.

**1. Hazard/Defect analysis not performed or available.**

The hazard and defect analysis is the foundation of the quality plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Firms must provide this analysis to the requesting Consumer Safety Officer in writing. If it is not provided and evidence suggests that it was performed but a written document is not available, check the Major deficiency. Otherwise, check the Serious deficiency.

**2. Hazard/Defect analysis not reassessed when indicated as necessary.**

Firms must reassess their hazard and defect analyses when information or other evidence indicates the need and at least yearly.

**3. HACCP/Defect Plan, SSOP's, and/or Quality Management Plan not followed.**

The Critical box should only be checked when non compliant product has been found as part of the product verification.

**4. Critical limits improperly identified.**

If evidence suggests that the critical limits were improperly identified but those identified were followed, check this deficiency.

**5. Critical limits not followed.**

Self Explanatory.

**6. Monitoring procedures not followed.**

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the firm is not in compliance with this item.

**7. Corrective actions not taken.**

A firm is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conducting of the QMP plan, the firm must file a corrective action report (Notice of Unusual Occurrence and Corrective Action--NUOCA). All other deficiencies may possibly be averted in this checklist if corrective action reports are filed for each problem or situation. Failure to file a corrective action report will be considered a failure to take a corrective action and the firm will then not be in compliance with this item.

**8. Verification procedures not followed.**

Verification procedures are those that provide for management to determine the overall effectiveness of the plan. Not following these procedures could ultimately cause the plan to fail or misidentify a hazard, defect, or control procedure. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a Serious level. This item should be

checked on a trend basis, not based on isolated incidences unless they are of such severity to warrant action.

## **B. RECORDS**

### **1. Records are not up-to-date.**

All records must be kept up-to-date. Entries must be made as they are measured. All time schedules outlined in the QMP plan must be maintained. Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc. If records are not up to date, the Major box for this deficiency should be checked.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, the Serious box for this deficiency should be checked.

### **2. Records are inaccurate.**

All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, the box for this deficiency should be checked. This deficiency will also be used for the compliance of product leaving the firm.

### **3. Records are not available for inspection.**

If the firm for any unreasonable amount of time does not surrender the applicable record for inspector review, they are not in compliance with this item. If portions of a record are not available, the firm is not in compliance with this item.

### **4. Any documents or records are falsified.**

This item is self-explanatory. However, intent on the part of the firm or its representatives must be shown. For example, if an item on a record was shown to be corrected with correction fluid or other means of obliteration, the inspector must show that someone with, full knowledge, changed the entry to reflect a value that was not the value measured or observed. Otherwise, this will be considered an inaccurate entry.

### **5. Inadequate information on records. (Facility name and location, etc.)**

Self Explanatory. Based on the required information stated in 21 CFR Part 123.

## **C. OTHER REQUIREMENTS**

### **1. HACCP plan not signed and/or dated by proper personnel.**

The plan must be signed and dated by a management official responsible for the operation of the facility. The plan must be signed upon implementation and at least once each year.

### **2. Hazard analysis, reassessment/modification of HACCP plan performed by untrained personnel.**

Per 21 CFR part 123, these duties are assigned only to properly trained personnel. For the QMP Program, properly trained will be any person who has passed the NMFS Certification Exam. However, failure of this element will not likely cause an immediate hazard or defect. Therefore it is rated as a Serious deficiency.

### **3. Record review performed by untrained personnel.**

Per 21 CFR part 123, these duties are assigned to only properly trained personnel. Failure of this element could lead to an immediate hazard or defect.

**4. Certified trained personnel not available.**

Each firm must employ a person who has been certified by NMFS for this program. At least one NMFS HACCP-certified person is required to be present during production. In addition, copies of all certified personnel's certificates must on file with the firm.

**5. Modification to QMP plan without approval.**

Any change in procedures whether they are written or not will be considered non-compliance by the firm for this item. This includes all procedures at critical control points, sanitation procedures, recall procedures verification procedures, and consumer complaint procedures. Exceptions will be allowed for those procedures the firm can justify that were necessary to avert or control a public safety or health situation provided a corrective action report is on file for the incident and a request for plan modification is filed with the servicing NMFS Regional Inspection Branch within a 24 hour period.

**Facility Sanitation**

**1. SAFETY OF PROCESS WATER**

Process water must be of very high quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

**1.1 Unsafe water supply.**

The water supply, including sea water, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency. Private supplies shall have testing performed at a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year.

**1.2 No protection against backflow, back-siphonage, or other sources of contamination.**

A facility will be in compliance when all cross-connections are eliminated, backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present.

**1.3 Inadequate supply of hot water.**

Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a luke-warm supply of water is present in sufficient quantities for the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.

**1.4 Ice not manufactured, handled, or used in a sanitary manner.**

A facility will be in compliance when potable water is used for manufacturing, when the manufacturing equipment is clean, and the ice only touches impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for food contact; and ice is not reused on ready-to-eat

product. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice received.

## **2. FOOD CONTACT SURFACES**

### **2.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned and sanitized; does not preclude product contamination or adulteration.**

Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it can be easily taken apart for regular cleaning and inspection. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

### **2.2 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary. (Product-contact surfaces)**

All product contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.

### **2.3 Product contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.**

Product contact surfaces must be cleaned using proper techniques to remove dirt and debris. Sanitizers must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance.

### **2.4 Processing or food handling personnel do not maintain a high degree of personal cleanliness.**

All persons, while in food preparation or handling areas shall wear clean outer garments, use clean cloths, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.

### **2.5 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.**

All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands must be sanitized using the company-provided hand dip stations.
2. Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
3. If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they

will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.

4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.
5. Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where food or food ingredients are exposed, or in areas used for food processing, storage of food ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.
6. Take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

### **3. PREVENTION OF CROSS CONTAMINATION**

#### **3.1 Grounds condition can permit contamination to enter the facility.**

There shall be no conditions on the grounds such as dusty roads or parking lots, mud puddles, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc. Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual inspections.

#### **3.2 Facility**

##### **3.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product contamination or adulteration.**

If the rooms (including restrooms and employee breakrooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

##### **3.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.**

There must be sufficient separation between different activities in the processing, packaging and handling of food products. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food surfaces if exposed. In addition, the layout of the facility should not be such that product contamination is likely due to heavy employee traffic through work areas.

Retail product displays should be arranged so that there is sufficient separation to assure that no cross-contamination can occur between raw, cooked, and live product.

#### **3.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.**

**3.3.1 Areas directly affecting product or packaging material.**

For those areas that will directly affect product or primary packaging materials, (packaging immediately surrounding product), the roof, ceiling, walls, floors, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

**3.3.2 Other.**

For areas in the facility other than in 3.1.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.

**3.4 Cleaning methods permit adulteration or contamination.**

Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizers, etc., during production.

**3.5 Finished product not properly covered or protected.**

**3.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-product contact surfaces)**

All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.3.1 above is insufficient and may allow indirect product contamination or adulteration.

**3.7 Non-product contact surfaces not cleaned before use.**

Non-product contact areas must also be cleaned prior to use. However, sanitizing is not required. This includes wall, ceilings, floors, and other room areas as well as equipment.

**4. HANDWASHING, HAND SANITIZING, AND TOILET FACILITIES**

**4.1 Hand washing and hand sanitizing stations not present or conveniently located.**

Hand washing and hand sanitizing stations must be present and located conveniently and in sufficient numbers to provide employees ease of their use.

**4.2 Improper disposal of Sewage.**

A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewerage system.

**4.3 Inadequate supplies.**

The restrooms must provide supplies such as toilet paper, soap, etc., sufficient enough to meet employees' needs.

**4.4 Insufficient number of functional toilets.**

The facility must have one operable, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required.

## **5. PROTECTION FROM ADULTERATION**

### **5.1 Condensation.**

#### **5.1.1 Areas directly affecting product or primary packaging material.**

If any condensation, overhead leaks, or water splash is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material, the facility is in non-compliance.

#### **5.1.2 Other**

Any areas other than those noted above where food is stored, handled, processed, packaged, or displayed shall be condensation-free. If condensation is noted in these areas, the facility shall be in non-compliance.

### **5.2 Adequate air exchange does not exist.**

A facility is in compliance when adequate air exchange exists to preclude the development of foul odors.

## **6. PROPER LABELING, STORAGE, AND USE OF TOXIC COMPOUNDS**

Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, machine lubricants, etc. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

A facility will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA or USDA approval.

### **6.1 Chemical(s) improperly used or handled.**

### **6.2 Chemical(s) improperly stored.**

### **6.3 Chemical(s) improperly labeled.**

## **7. CONTROL OF EMPLOYEE HEALTH CONDITIONS**

### **7.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.**

No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.

## **8. EXCLUSION OF PESTS**

The presence of rodents, insects, and other animals in the facility must not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

**8.1 Harborage and attractant areas present.**

The facility and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are properly constructed.

**8.2 Pest control measures not effective.**

**8.2.1 Exclusion**

Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4 ") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in food establishments. Strip curtains must run the entire width of the opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where food is transferred or processed.

**8.2.2 Extermination**

Birds--Nesting areas must be eliminated.

Insects--There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags that may be excessive. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.

**8.3 Inadequate disposal of processing waste.**

A facility is in compliance with regard to processing wastes when they are placed in proper containers, placed at appropriate locations throughout the plant, and removed frequently.

**8.4 Inadequate housekeeping.**

Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

# **NOAA Seafood Inspection Program Quality System Standard**

## **1.0 MANAGEMENT RESPONSIBILITY**

### **1.1 Quality Policy**

Management with executive responsibility in the firm must endorse a policy statement that fully reflects company policy and objectives relating to quality (including the control of the safety, wholesomeness and integrity of the product), and its commitment to quality assurance. The policy must consider the expectations and needs of the customer. There must be a procedure to ensure the quality policy is known, understood, implemented, and maintained at all levels of the company.

### **1.2 Organization**

The company shall establish and maintain an adequate organizational structure to ensure that the applicable fish and fishery products are designed and produced in accordance with the requirements of this standard.

#### **1.2.1 Responsibility and Authority**

The manufacturer shall establish and document the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality, and provide the independence and authority necessary to perform tasks including but not limited to:

- a) Initiate action to prevent the occurrence of any nonconformities relating to the product, process, and quality system;
- b) Identify and record any problems relating to the product, process, and quality system;
- c) Initiate, recommend, or provide solutions through designated channels;
- d) Verify the implementation of solutions;
- e) Control further processing or delivery of nonconforming product until the deficiency or deficiencies have been corrected.

#### **1.2.2 Resources**

Each manufacturer shall provide adequate resources, including the assignment of trained

personnel, for management, performance of work, and verification activities, including internal quality audits, to meet the requirements of this standard.

#### **1.2.3 Management Representative**

Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority and responsibility for:

- a) Ensuring that quality system requirements are effectively established, implemented, and effectively maintained in accordance with this standard; and
- b) Reporting on the performance of the quality system to management with executive responsibility for review and as a basis for improvement of the quality system.
- c) liaison with external parties on matters relating to the quality system.

### **1.3 Management Review**

Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this standard and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

## **2.0 QUALITY SYSTEM**

### **2.1 General**

The manufacturer shall establish, document, and maintain a quality system that ensures all applicable fish and fishery products conform to specified product standards and requirements and this standard. The manufacturer shall prepare a quality manual covering the requirements of this standard. The quality manual shall make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

## **2.2 Quality System Procedures**

The manufacturer shall:

- a) prepare documented procedures consistent with the requirements of this standard and the manufacturer's stated quality policy, and
- b) effectively implement the quality system and its documented procedures.

The range and detail of the procedures will depend on the complexity of the work, the methods used, and the skills and training needed by the personnel involved in carrying out the referenced activity. Documented procedures may make reference to work instructions that define how an activity is performed.

## **2.3 Quality Planning**

The manufacturer shall establish how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of the quality system and shall be documented in a format to suit the method of operation. The manufacturer shall give consideration to the following activities, as appropriate, in meeting the specified standards and requirements for fish and fishery products:

- a) the quality and safety objectives to be attained;
- b) the specific allocation of responsibilities and authority during the development, implementation, and maintenance of the system;
- c) the specific procedures, methods and work instructions to be applied;
- d) the specific tasks required for application of a HACCP system;
- e) suitable testing, inspection, examination and audit programs at appropriate stages;
- f) a method for making changes and modifications in a HACCP or quality plan as they are developed and implemented;
- g) other measures to meet necessary objectives such as methods for meeting requirements of Good Manufacturing Practices (GMPs).

## **3.0 CONTRACT REVIEW**

### **3.1 General**

The manufacturer shall establish and maintain documented procedures for contract review and for the coordination of these activities.

### **3.2 Review**

Before submission or the acceptance of a contract or order (statement of requirement), the contract or order shall be reviewed by the manufacturer to ensure that:

- a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the manufacturer shall ensure that the order requirements are agreed before their acceptance;
- b) any differences of understanding of the contract or accepted order requirements are resolved;
- c) the manufacturer has the capability to meet the contract or accepted order requirements.

### **3.3 Amendment to Contract**

The manufacturer shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the organization.

### **3.4 Records**

Records of contract reviews shall be maintained.

## **4.0 DESIGN CONTROL**

### **4.1 General**

The manufacturer shall establish and maintain documented procedures for translating the customer's specifications and requirements into technical specifications for raw materials, processing, packaging, storage, etc., and their verification. The specifications must also cover buildings, equipment and facilities (internal and external) where relevant. Responsibility for developing these specifications must be assigned to specific people and there must be a planned approach to each activity.

### **4.2 Design and Development Planning**

The manufacturer shall establish and maintain

plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall be reviewed, updated, and approved as design and development evolves. These activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as necessary.

#### **4.3 Organizational and Technical Interfaces**

The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process.

#### **4.4 Design Input**

The manufacturer shall establish and maintain procedures to ensure that the design requirements relating to the applicable fish and fishery product are appropriate and address the intended use by the purchaser or consumer. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

#### **4.5 Design Output**

The manufacturer shall establish and maintain procedures for defining and documenting design output in terms that can be verified. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the safety, wholesomeness, economic integrity, and quality of the fish or fishery product are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

#### **4.6 Design Review**

The manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the product's

design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. Records of such reviews shall be maintained.

#### **4.7 Design Verification**

The manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the verification shall be recorded.

#### **4.8 Design Validation**

Design validation shall be performed to ensure that product conforms to defined user needs, requirements, and intended use. Design validation shall include risk analysis where appropriate. Validation is normally performed on the final product, but may be performed in earlier stages prior to product completion. Multiple validations may be necessary if there are different intended end uses.

#### **4.9 Design Changes**

All design changes and modifications shall be identified, documented, reviewed, and approved by authorized personnel before their implementation.

### **5.0 DOCUMENT AND DATA CONTROL**

#### **5.1 General**

The manufacturer shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this standard including, to the extent applicable, documents of external origin such as standards and customer specifications. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

#### **5.2 Document and Data Approval and Issue**

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the

current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

- a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

### **5.3 Document and Data Changes**

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

## **6.0 PURCHASING**

### **6.1 General**

The manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

### **6.2 Evaluation of Suppliers, Contractors, and Consultants**

The manufacturer shall establish and maintain the requirements (including safety, wholesomeness, economic integrity, and quality requirements) that must be met by suppliers, contractors, and consultants. The manufacturer shall:

- a) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The

evaluation shall be documented.

- b) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.
- c) Establish and maintain quality records of acceptable suppliers, contractors, and consultants.

### **6.3 Purchasing Data**

The manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished product. The manufacturer shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

### **6.3 Verification of Purchased Product**

#### **6.3.1 Supplier Verification at Subcontractor's Premises**

Where the manufacturer proposes to verify purchased product at the subcontractor's premises, the manufacturer shall specify verification arrangements and the method of product release in the purchasing documents.

#### **6.3.2 Customer Verification of Subcontracted Product**

Where specified in the contract, the manufacturer's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises, and the manufacturer's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the

manufacturer as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

## **7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT**

The manufacturer shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer.

Verification by the manufacturer does not absolve the customer of the responsibility to provide acceptable product.

## **8.0 PRODUCT IDENTIFICATION AND TRACEABILITY**

### **8.1 Identification**

The manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation.

### **8.2 Traceability**

The manufacturer shall establish and maintain documented procedures for unique identification of individual product, batches, or lots. This identification shall be recorded.

## **9.0 PROCESS CONTROL**

The manufacturer shall identify and plan the production of processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- a) documented procedures defining the manner of production where the absence of such procedures could adversely affect quality;
- b) use of suitable equipment, and a suitable working environment;

- c) compliance with reference standards/codes, quality plans, and/or documented procedures;
- d) monitoring and control of suitable process parameters and product characteristics;
- e) the approval of processes and equipment, as appropriate;
- f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);
- g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.

Records shall be maintained for qualified processes, equipment, and personnel, as appropriate.

## **10.0 INSPECTION AND TESTING**

### **10.1 General**

The manufacturer shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

### **10.2 Receiving Inspection and Testing**

**10.2.1** The manufacturer shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan and/or

documented procedures.

**10.2.2** In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

**10.2.3** Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

### **10.3 In-process Inspection and Testing**

The manufacturer shall:

- a) inspect and test the product as required by the quality plan and/or documented procedures;
- b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 10.3a.

### **10.4 Final inspection and testing**

The manufacturer shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

### **10.5 Inspection and Test Records**

The manufacturer shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

## **11.0 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT**

The manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. The manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented.

These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

## **12.0 INSPECTION AND TEST STATUS**

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used, or installed.

## **13.0 CONTROL OF NONCONFORMING PRODUCT**

### **13.1 General**

The manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

### **13.2 Review and Disposition of Nonconforming Product**

The manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

The manufacturer shall establish and maintain

procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented.

## **14.0 CORRECTIVE AND PREVENTIVE ACTION**

### **14.1 General**

The manufacturer shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The manufacturer shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

### **14.2 Corrective Action**

The procedures for corrective action shall include:

- a) the effective handling of customer complaints and reports of product nonconformities;
- b) investigation of the cause of nonconformities relating to product, process, and quality System, and recording the results of the investigation (see 16);
- c) determination of the corrective action needed to eliminate the cause of nonconformities;
- d) application of controls to ensure that corrective action is taken and that it is effective.

### **14.3 Preventive Action**

The procedures for preventive action shall include:

- a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records,

service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;

- b) determination of the steps needed to deal with any problems requiring preventive action;
- c) initiation of preventive action and application of controls to ensure that it is effective;
- d) confirmation that relevant information on actions taken is submitted for management review (see 1.3).

## **15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY**

### **15.1 General**

The manufacturer shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

### **15.2 Handling**

The manufacturer shall provide methods of handling product that prevent damage or deterioration.

### **15.3 Storage**

The manufacturer shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

### **15.4 Packaging**

The manufacturer shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

### **15.5 Preservation**

The manufacturer shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

### **15.6 Delivery**

The manufacturer shall arrange for the protection

of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

## **16.0 CONTROL OF QUALITY RECORDS**

The manufacturer shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

Records may be in the form of any type of media, such as hard copy or electronic media.

## **17.0 INTERNAL QUALITY AUDITS**

The manufacturer shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area

shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 16).

## **18.0 TRAINING**

The manufacturer shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 16).

## **19.0 SERVICING**

Where servicing is a specified requirement, the manufacturer shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

## **20.0 STATISTICAL TECHNIQUES**

### **20.1 Identification of Need**

The manufacturer shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

### **20.2 Procedures**

The manufacturer shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 20.1.